10 CIV 1851

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MERCK, SHARP & DOHME CORP. and BRISTOL-MYERS SQUIBB COMPANY,

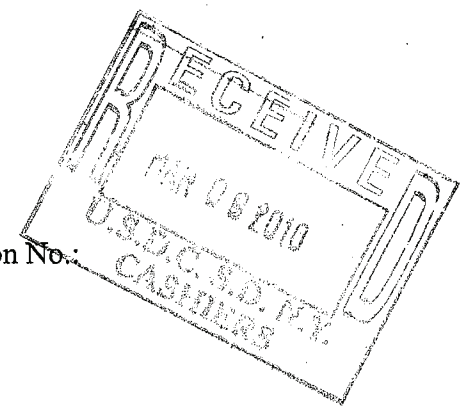
Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Defendants.

Civil Action No.:



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck, Sharp & Dohme Corp. ("Merck") and Bristol-Myers Squibb Company ("BMS") (collectively, "Plaintiffs") for their Complaint against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva"), hereby allege as follows:

Nature of Action

1. This is an action for patent infringement under the Patent Laws of the United States, Title 35, United States Code.

The Parties

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey having a principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

3. Plaintiff BMS is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 345 Park Avenue, New York, NY 10154-0037.

4. On information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454.

5. On information and belief, defendant Teva Pharmaceutical Industries, Ltd. ("Teva Industries") is a corporation organized and existing under the laws of Israel having a principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

6. On information and belief, Teva USA is a wholly-owned subsidiary of, and has common officers and directors with, Teva Industries.

7. On information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization, cooperation, participation, assistance of, and at least in part for the benefit of, Teva Industries.

Jurisdiction and Venue

8. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Teva USA and Teva Industries.

10. On information and belief, Teva USA derives substantial revenue from selling various products and doing business throughout the United States, including in New York and this District.

11. On information and belief, Teva USA is registered to do business with the New York State Division of Corporations, and Corporate Creations Network Inc., 15 North Mill Street, Nyack, New York 10960 is authorized to accept service on behalf of Teva USA.

12. On information and belief, Teva Industries manufactures bulk pharmaceuticals and pharmaceutical products that are sold, including sold by Teva USA, throughout the United States, including in this District.

13. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

Background

14. BMS is the holder of New Drug Application ("NDA") No. 21-360, which relates to tablets containing 600 mg of efavirenz. On February 1, 2002, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-360 for the treatment of HIV-1 infection in combination with other antiretroviral agents. These tablets are prescribed and sold in the United States under the trademark Sustiva®.

15. BMS and Gilead Sciences, Inc. ("Gilead") formed a joint venture, Bristol-Myers Squibb & Gilead Sciences, LLC, to co-formulate Sustiva® and Gilead's Truvada® (emtricitabine and tenofovir disoproxil fumarate) into a once daily combination product.

16. Gilead is the holder of NDA No. 21-937, which relates to tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On July 12, 2006, the FDA approved the use of the tablets described in NDA No. 21-

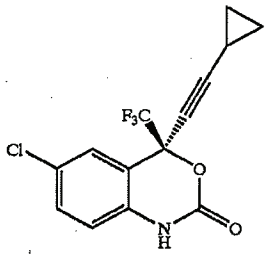
937 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Atripla®.

17. United States Patent No. 6,639,071 (the "'071 Patent," copy attached as Exhibit A), entitled "Crystal Forms of (-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4,Dihydro-2H-3,1-Benzoxazin-2-One," was duly and legally issued by the United States Patent and Trademark Office on October 28, 2003. The '071 Patent claims, *inter alia*, efavirenz (the active ingredient in Sustiva® and one of the active ingredients in Atripla®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Sustiva® and Atripla®.

18. United States Patent No. 6,939,964 (the "'964 Patent," copy attached as Exhibit B), entitled "Crystal Forms of (-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4,Dihydro-2H-3,1-Benzoxazin-2-One," was duly and legally issued by the United States Patent and Trademark Office on September 6, 2005. The '964 Patent claims, *inter alia*, efavirenz (the active ingredient in Sustiva® and one of the active ingredients in Atripla®), and is listed in the FDA Orange Book for Sustiva® and Atripla®.

19. The '071 and '964 Patents are owned by Merck.

20. Efavirenz is a compound that has a molecular formula of $C_{14}H_9ClF_3NO_2$, and which has the following chemical structure:



21. Efavirenz can be referred to by any of several chemical names. The chemical name given to efavirenz in the Sustiva® label is "(S)-6-chloro-4-(cyclopropylethynyl)-1,4-dihydro-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one." The chemical name recited for efavirenz in the '071 Patent is "(-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4,Dihydro-2H-3,1-Benzoxazin-2-One."

22. The named inventors on the '071 and '964 Patents are Louis S. Crocker, Joseph L. Kukura, II, Andrew S. Thompson, Christine Stelmach, and Steven D. Young.

23. Louis S. Crocker, Joseph L. Kukura, II, Andrew S. Thompson, Christine Stelmach, and Steven D. Young assigned the '071 and '964 Patents to Merck & Co., Inc. The '071 and '964 Patents were later assigned to Merck.

24. Pursuant to an agreement entered into between Merck and The DuPont Merck Pharmaceutical Company ("DPMC"), whereas DPMC was subsequently acquired by BMS, BMS has substantial rights in the '071 and '964 Patents, including but not limited to, rights associated with being a licensee of the '071 and '964 Patents, and the right to sue for infringement of the '071 and '964 Patents. BMS also derives revenue from licensing the '071 and '964 Patents to Gilead for the sale of Atripla®.

COUNT 1
Infringement of U.S. Patent No. 6,639,071 (ANDA No. 91-215)

25. Plaintiffs repeat and reallege paragraphs 1-24 above as if set forth herein.

26. On information and belief, Teva submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 91-215, to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets

containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

27. On information and belief, ANDA No. 91-215 seeks approval to manufacture, use, sell and import efavirenz for the purpose of treating HIV infection in combination with other antiretroviral agents in adults.

28. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Atripla® Notice Letter"), Teva notified Plaintiffs that it had submitted ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '071 Patent.

29. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiffs that, as a part of ANDA No. 91-215, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '071 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that, in its opinion and to the best of its knowledge, the subject patent, here the '071 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

30. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1 and 6-7 of the '071 Patent are invalid and that Claims 2-5 and 8-11 of the '071 Patent would not be infringed by the commercial manufacture, use, sale and importation of its proposed product that is the subject of ANDA No. 91-215.

31. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '071 Patent's expiration, Teva has committed an act of infringement of the '071 Patent under 35 U.S.C. § 271(e)(2).

32. On information and belief, Teva lacked a good faith basis for alleging invalidity and non-infringement when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '071 Patent.

33. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-215 will infringe, induce infringement and/or contributorily infringe one or more claims of the '071 Patent.

COUNT 2
Infringement of U.S. Patent No. 6,939,964 (ANDA No. 91-215)

34. Plaintiffs repeat and reallege paragraphs 1-24 and 26-27 above as if set forth herein.

35. In the January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) that it had submitted ANDA No. 91-215 to the FDA

seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '964 Patent.

36. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiffs that, as a part of its ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '964 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that, in its opinion and to the best of its knowledge, the subject patent, here the '964 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

37. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-4 of the '964 Patent are invalid and that Claims 5-14 of the '964 Patent would not be infringed by the commercial manufacture, use, sale and importation of its proposed product that is the subject of ANDA No. 91-215.

38. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '964 Patent's expiration, Teva has committed an act of infringement of the '964 Patent under 35 U.S.C. § 271(e)(2).

39. On information and belief, Teva lacked a good faith basis for alleging invalidity and non-infringement when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '964 Patent.

40. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Teva seeks approval in ANDA No. 91-215 will infringe one or more claims of the '964 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration of the '071 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(b) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration of the '964 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the '071 Patent remains valid, enforceable and has been infringed by Teva;

(d) A judgment declaring that the '964 Patent remains valid, enforceable and has been infringed by Teva;

(e) A permanent injunction against any infringement of the '071 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(f) A permanent injunction against any infringement of the '964 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(g) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(k) Such other relief as this Court may deem proper.

March 9, 2010

Respectfully submitted,

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